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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,122	07/07/2003	Santu Bandyopadhyay	02506.00P600.1	7170

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/613,122	BANDYOPADHYAY ET AL.	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed January 3, 2007 presents remarks and arguments submitted to the office action mailed July 5, 2006 is acknowledged.

Applicant's amendments submitted January 3, 2007 is acknowledged wherein claims 1-18 are amended.

Applicant's arguments over the 35 U.S.C. 112 first paragraph rejection of claims 17-18 is found persuasive due to amendment of claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1-4 and 6-18 over Bandmpadhyay et al. (IPCT/1NOO/00118), in view of applicants admission, is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1-18 over Bandmpadhyay et al. (IPCT/1NOO/00118), in view of Zon et al. (US Pat. No. 5700927) and Bandyopadhyay et al. (U.S. Patent Application Publication No. 2003/0229140) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicants filing of a Terminal Disclaimer for the ODP rejection made over Patent No. 7045157, 6853244, co-pending Application No. 11/222815 and 11/117545 will be withdrawn once the Terminal Disclaimer is approved.

The ODP rejection made over co-pending Application No. 10/338,689 is withdrawn due its the abandonment.

The rejection is restated below for applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bandmpadhyay et al. (IPCT/1NOO/00118), in view of applicants admission.

Bandmpadhyay et al. ('118) teaches method for the treatment of Myeloid Leukemia (acute myeloid leukemia and chronic myeloid leukemia) in subjects such as animals, including human beings, which comprise administering to said subjects a pharmaceutical composition comprising an effective amount a betel leaf extract ('118; page 2 lines 25-29 and p. 3 lines 4-6), recited in claim 3. Betal extract contains the compounds chlorogenic acid (CA) and 3-o-p-Coumaryl (PCQ).

The reference further teaches that the effective amount of betel leaf extract is between 5 to 20 m/kg of body weight per day ('118; p. 3 line 25); and the composition may be administered upon alternate days for at least three weeks, preferably one month ('118; p. 3 line 27), meeting the limitation of claim 7. The compositions may further comprise additives including nutrients comprising proteins, carbohydrates, sugar, talc, magnesium stearate, cellulose, calcium carbonate, starch-gelatin paste and/or pharmaceutically acceptable carriers ('118; p. 3 line 10-15)," as recited in claim 4. The

routes by which the compositions may be administered are "orally or intramuscularly" ('118; p. 3 line 16), recited in claim 6.

Bandmpadhyay et al. ('118) does not expressively teach the extract components chlorogenic acid (CA) or 3-o-p-coumaryl quinic acid (PCQ). Additionally, the prior art reference does not specifically teach the ratio of CA and PCQ (recited in claim 5) nor the percentage growth inhibition of Erythroleukemia cells, promonocyte cells, and CML's leukemic cells, as recited in claims 8-18.

However, the prior art reference teaches that the extracts are from the same source as used by applicant and that the extracts have the same efficacy of treating myeloid leukemia. Also, the observation of the specific inhibition percentages that would have resulted from practicing the methods taught by Bandyopadhyay ('118) is a matter that does not impart patentable moment to the claimed subject matter. One of ordinary skill in the art, by virtue of the very teaching that the compounds are effective for the treatment of myeloid leukemia, would have been imbued with at least a reasonable expectation that the growth of cells associated with myeloid leukemia would have been inhibited to some degree and the determination of the percentage inhibition for the compounds would have been a matter well within the purview of the skilled artisan.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bandmpadhyay et al. (IPCT/1NOO/00118), in view of Zon et al. (US Pat. No. 5700927) and Bandyopadhyay et al. (U.S. Patent Application Publication No. 2003/0229140)

Bandmpadhyay et al. ('118) is as discussed above.

Bandmpadhyay et al. ('118) does not expressively teach the extract components chlorogenic acid (CA) or 3-o-p-coumaryl quinic acid (PCQ). Additionally, the prior art reference does not specifically teach the ratio of CA and PCQ (recited in claim 5) nor the percentage growth inhibition of Erythroleukemia cells, promonocyte cells, and CML's leukemic cells, as recited in claims 8-18.

In the Background of the Invention, Zon et al. teaches the relationship between erythroleukemia and promonocytes (see column 1 and 2).

Additionally, Bandyopadhyay et al. ('140) teaches a pharmaceutical composition useful for treating chronic myeloid leukemia comprising chlorogenic acid and/or 3-o-p-coumaryl quinic acid, i.e., the latter being a chlorogenic acid analog, in an amount of from 1 and 50 mg per kg body weight/day, wherein the chlorogenic analog may be obtained either from natural or synthetic sources, wherein the composition may contain various additives of the type claimed, wherein the composition may be administered through oral, intravenous, intramuscular or subcutaneous routes and wherein the composition may be administered for a period ranging from four to twelve weeks (page 2, sections (0027 - 0032)). suitable for oral administration (col. 9, line 66 - col. 10, line 25).

The prior art reference teaches that the extracts are from the same source as used by applicant and that the extracts have the same efficacy of treating myeloid leukemia. Further, the relationship between the cells affected by myeloid leukemia is taught by the Zon et al. reference. Therefore, the observation of the specific inhibition percentages that would have resulted from practicing the methods taught by

Bandyopadhyay ('118) is a matter that does not impart patentable moment to the claimed subject matter. One of ordinary skill in the art, by virtue of the very teaching that the compounds are effective for the treatment of myeloid leukemia, would have been imbued with at least a reasonable expectation that the growth of cells associated with myeloid leukemia would have been inhibited to some degree and the determination of the percentage inhibition for the compounds would have been a matter well within the purview of the skilled artisan. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of Badmpadhyay et al. compound by routine experimentation (see 2144.05 11) because the prior art teaches the same composition in treatment of myeloid leukemia. The motivation to optimize the dose range of the Badmpadhyay et al. final formulation is because he would have had a reasonable expectation of success in achieving the safest clinical outcome in treating patients with myeloid leukemia.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 6, and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Patent No. 7,045,157 and claims 21-22, 24-25, and 28 of co-pending application no. 11/222815. Although the conflicting claims are not identical, they are not patentably distinct from each other because: the Patent claims entitle a method differently than here, i.e., “method of inducing and assaying IFNy production” and “use of betel leaf extract or a composition comprising effective amount of betel leaf extract for inducing IFN-y from human peripheral blood mononuclear cells or as a Th1 type immunomodulator” in the patent claims and copending claims vs. “for treating chronic myeloid leukemia" in the present claims. However, Dunussi-Joannopoulos et al. teaches Th1 cells secrete IL-2 and IFN-γ induce cellular immune responses useful in immunotherapies for AML. The patent and co-pending claims do not expressly require chlorogenic acid and 3-o-p-Coumaryl quinic acid as is required in the present claims. However, the patent and co-pending claims require a betel leaf extract which contain both chlorogenic acid and 3-o-p-Coumaryl quinic acid.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of Patent No. 6852344. Although the conflicting claims are not identical, they are not patentably distinct from each other because: Both the current and patent claims encompass the treatment of chronic myeloid leukemia and there is substantial overlap with regard to the type of leukemia being treated. The patented claims do not expressly require chlorogenic acid as is required in the present claims. However, the patent claims require a betel leaf extract which contain both chlorogenic acid and 3-o-p-Coumaryl quinic acid.

Claims 1, 4, 6, and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24, 26, 28-29 and 30 of Application No. 11/174545. Although the conflicting claims are not identical, they are not patentably distinct from each other because: Both the current and co-pending claims encompass the treatment of chronic myeloid leukemia and there is substantial overlap with regard to the type of leukemia being treated. The copending claims do not expressly require betel leaf extract as is required in the present claims. However, the copending claims require chlorogenic acid a betel leaf extract.

Response to Arguments

Applicant's arguments January 3, 2007 have been fully considered but they are not persuasive for the reasons set forth below.

Examiner respectfully reiterates that the disclosure of Bandmpadhyay et al. (IPCT/1NOO/00118) has a prior art date under 35 U.S.C. 102 (b). The invention was patented or described in a printed publication in this or a foreign country or in public use

or on sale in this country, more than one year prior to the date of application for patent in the United States. Hence, the PCT document's date is valid and the rejection stands.

Applicant argues that "there is no factual predicate of record whatsoever for the Examiner's assertion that one of ordinary should or would be "imbued with at least a reasonable expectation that the growth of cells associated with myeloid leukemia would have been inhibited to some degree," is unpersuasive. Bandmpadhyay et al. (IPCT/1NOO/00118) teaches method for the treatment of Myeloid Leukemia (acute myeloid leukemia and chronic myeloid leukemia) in subjects including human beings, which comprise administering to said subjects a pharmaceutical composition comprising an effective amount a betel leaf extract ('118; page 2 lines 25-29 and p. 3 lines 4-6). Additionally, Zon et al. teaches the relationship between erythroleukemia and promonocytes. Therefore, one of ordinary skill in the art, by virtue of the very teaching that the compounds are effective for the treatment of myeloid leukemia, would have been imbued with at least a reasonable expectation that the growth of cells associated with myeloid leukemia would have been inhibited to some degree and the determination of the percentage inhibition for the compounds would have been a matter well within the purview of the skilled artisan.

The arguments are not persuasive and the rejection is made **FINAL**.

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER